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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,441	12/08/2003	Rajeeva Singh	A8689	3309

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,441	SINGH ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This election/restriction requirement sets forth multiple elections applicable to the Inventions of Groups I-III (see item nos. 2-4 below).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18 and 23, drawn to a composition comprising an antibody or antibody fragment that specifically binds insulin-like growth factor-I receptor and a second therapeutic agent, classified in class 530, subclass 387.1.

II. Claims 19, 22, 24, 26, 27, 30 and 31, drawn to a method for inhibiting the growth of a cancer cell, classified in class 435, subclass 7.23.

III. Claims 20-22, 25 and 28-31 drawn to a method for treating a patient having a cancer, classified in class 424, subclass 130.1.

3. This application contains claims in Groups I-III directed to the following patentably distinct species, wherein a second therapeutic agent is selected from the list consisting of:

A. Docetaxel

B. Paclitaxel

C. Doxorubicin

D. Epirubicin

E. Cyclophosphamide

F. Trastuzumab (Herceptin)

G. Capecitabine

H. Tamoxifen

I. Toremifene

J. Letrozole

K. Anastrozole

L. Fulvestrant

M. Exemestane

N. Goserelin

O. Oxaliplatin

P. Carboplatin

Q. Cisplatin

R. Dexamethasone

S. Antide

T. Bevacizumab (Avastin)

U. 5-fluorouracil

V. Leucovorin

W. Levamisole

X. Irinotecan

Y. Etoposide

Z. Topotecan

AA. Gemcitabine

BB. Vinorelbine

CC. Estramustine

DD. Mitoxantrone

EE. Abarelix

FF. Zoledronate

GG. Streptozocin

HH. Rituximab (Rituxan)

II. Idarubicin

JJ. Busulfan

KK. Chlorambucil

LL. Fludarabine

MM. Imatinib

NN. Cytarabine

OO. Ibritumomab (Zevalin)

PP. Tositumomab (Bexxar)

QQ. Interferon alpha-2b

RR. Melphalam

SS. Bortezomib (Velcade)

TT. Altretamine

UU. Asparaginase

VV. Gefitinib (Iressa)

WW. Erlonitib (Tarceva)

XX. Anti-EGF receptor antibody (Cetuximab, Abx-EGF)

YY. An epothilone

ZZ. Camptothecin

The species are independent or distinct because these species are a group of "diverse agents" as stated on page 26 of the specification and, as such, would require separate searches to determine patentability for each species composition, so restriction as required is proper.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from A-ZZ in addition to electing one of Group I-III for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 7-16 are generic for Group I, Claims 19 and 24 are generic for Group II and Claims 20 and 25 are generic for Group III.

4. Additionally, this application contains claims in Group II and Group III directed to a second patentably distinct species: a treatment for a cancer selected from the cancers consisting of:

i. breast cancer

ii. colon cancer

iii. ovarian carcinoma

iv. osteosarcoma

v. cervical cancer

vi. prostate cancer

vii. lung cancer

viii. synovial carcinoma

ix. pancreatic cancer

x. melanoma

xi. multiple myeloma

xii. neuroblastoma

xiii. rhabdomyosarcoma

The species are independent or distinct because they differ in the method objectives. In the instant case, the cancers listed do not have a common origin, a treatment for one would not necessarily work one for the other and the method objectives would be to treat the specific cancer of the patient. Therefore, separate searches would be required to determine patentability for each method of treatment, so restriction as required is proper.

If applicant elects Group II or Group III, applicant is further required under 35 U.S.C. 121 to elect a single disclosed species in the above list from i-xiii in addition to a single disclosed species in the list from A-ZZ for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 19 is generic for Group II and Claim 20 and 21 are generic for Group III.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consistent with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The methods of Inventions of Group II and Group III differ in the method objectives, method steps and parameters and endpoints. The invention of Group II recites a method of inhibiting the growth of a cancer cell. The invention of Group III recites a method for treating a patient having a cancer. Thus, the inventions of Groups II and III are separate and distinct in having different method objectives, method steps and parameters and endpoints and are patentably distinct.

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition of Group I could be used in the materially different process of Group III and vice versa. Therefore, Group I is distinct from Group II and Group III.

The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-III are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643